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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,300	04/20/2001	John R. Wells	70869-0089	5192

7590 08/29/2002

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EXAMINER
COOLEY, CHARLES E

ART UNIT	PAPER NUMBER
1723	5

DATE MAILED: 08/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/838,300	Wells et al.
Examiner	**Art Unit**
Charles Cooley	1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-47 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-47 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

OFFICE ACTION

Assignee

1. This application is objected to under 37 CFR 1.172(a) as lacking the written consent of all assignees owning an undivided interest in the patent. The consent of the assignee must be in compliance with 37 CFR 1.172. See MPEP § 1410.01.

A proper assent of the assignee in compliance with 37 CFR 1.172 and 3.73 is required in reply to this Office action. Note the transmittal form filed with the application indicates the original patent is assigned.

Surrender of Patent

2. The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

Reissue Oath/Declaration

3. The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

It does not state that the person making the oath or declaration has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration.

4. The reissue oath/declaration filed with this application is defective because it fails to identify at least one specific error which is relied upon to support the reissue application. See 37 CFR 1.175(a)(1) and MPEP § 1414. Any error in the claims must be identified by reference to specific claim(s) and the specific claim language containing the error. See MPEP § 1414(II).

5. Claims 1-47 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the declaration is set forth in the discussion above in this Office action.

Drawings

6. Requirements for drawings in reissue applications are found in 37 CFR 1.174 and MPEP 1413.

Specification

7. The abstract and title are acceptable.

8. The amended title of the invention is acceptable.

Claim Rejections - 35 U.S.C. § 112, first paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 32-37, 39, and 43-47 are rejected under 35 U.S.C. § 112, first paragraph, as not enabling.

MPEP 2172.01: Unclaimed Essential Matter

11. A claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may be rejected under 35 U.S.C. 112, first paragraph, as not enabling. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). See also MPEP § 2164.08(c). Such essential matter may include missing elements, steps or necessary structural cooperative relationships of elements described by the applicant(s) as necessary to practice the invention.

12. Claims 32-37, 39, and 43-47 are not enabling because claim 32 sets forth in the preamble a "method for treating physiological products" (and similar wording in the preambles of claims 35 and 43) yet the bodies of the claims fail to include the necessary steps to practice the invention of treating physiological products or fluids. Accordingly, the steps necessary to practice the invention of treating physiological products or fluids but not included in the claims are not enabled by the disclosure.

Since the enabling disclosure of the specification is not commensurate in scope with the claimed subject matter, claims 32-37, 39, and 43-47 are based on an insufficient disclosure. Furthermore, since claims 32-37, 39, and 43-47 lack the essential steps to perform the methods recited in the preambles, the rejection under the enablement provision of 35 U.S.C. 112 is considered proper.

Claim Rejections - 35 U.S.C. § 112, second paragraph

13. Claims 32-37, 39, and 43-47 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The second paragraph of 35 USC 112 requires a claim to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Under *In re Hammack*, 166 USPQ 204 (CCPA 1970) and *In re Moore*, 169 USPQ 236 (CCPA 1971), claims must be analyzed to determine their metes and bounds so that it is clear from the claim language what subject matter the claims encompass. This analysis must be performed in light of the applicable prior art and the disclosure. The definiteness of the claims is important to allow others who wish to enter the market place to ascertain the boundaries of protection that are provided by the claims. *Ex parte Kristensen*, 10 USPQ 2d 1701, 1703 (BPAI 1989). Claims 32-37, 39, and 43-47 fail to particularly

point out and distinctly claim the subject matter which applicant regards as the invention and are therefore indefinite for the following reasons:

Claims 32-37, 39, and 43-47 are rejected as vague and incomplete for omitting essential matter including missing steps necessary to practice the invention (MPEP 2172.01).

Claims 32-37, 39, and 43-47 fail to particularly point out and distinctly claim the subject matter which applicant regards as the invention because claim 32 sets forth in the preamble a "method for treating physiological products" (and similar wording in the preambles of claims 35 and 43) yet the bodies of the claims fail to further particularly point out and distinctly claim the method steps which achieve the method set forth in the preamble - see MPEP 2173.05(q) reproduced below:

MPEP 2173.05(q)

Attempts to claim a process without setting forth any steps involved in the process generally raises an issue of indefiniteness under 35 U.S.C. 112, second paragraph. *Ex parte Erlich*, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986).

Although a claim should be interpreted in light of the specification disclosure, it is generally considered improper to read limitations contained in the specification into the claims. See *In re Prater*, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969) and *In re Winkhaus*, 527 F.2d 637, 188 USPQ 129 (CCPA 1975), which discuss the premise that

one cannot rely on the specification to impart limitations to the claim that are not recited in the claim.

Accordingly, it is not seen how the "providing steps" of claims 32, 35, and 43 sets forth steps which accomplish the methods sets forth in the preambles thereof, namely treating physiological products or fluids.

* * *

Claim 39, line 2: does "a centrifuge rotor" have any relationship to the "centrifuge" recited in claim 38?

Claim 42, line 2: does "a centrifuge rotor" have any relationship to the "centrifuge" recited in claim 38?

Claim 47, line 1: the preamble of this claim is not consistent with the preambles of the other claims which depend from claim 43.

14. Each pending claim should be thoroughly reviewed such that these and any other informalities are corrected so the claims may particularly point out and distinctly claim the subject matter which applicant regards as the invention, as required by 35 U.S.C. § 112, second paragraph.

Claim Rejections - 35 U.S.C. § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

16. Claims 32, 33, 34, 35, 36, 37, 38, and 39 are rejected under 35 U.S.C. § 102(b) as being anticipated by Raccuglia et al. (USP 3,190,546).

The patent to Raccuglia et al. discloses a method for treating products or fluids including biological substances and blood (Col. 1, lines 19-39) and a system to perform the method shown in Figs. 8-11 comprising the steps of providing a centrifuge 212 with a rotor 214; providing a walled and closed container 110, 112 (Figs. 8-9) having a closed first chamber 114 and a closed second chamber 116; providing a bridge 166, 162, 141, 140, 168, 164, 153, 152 which forms a fluid path for allowing fluid communication between the chambers 114 and 116; the centrifuge being provided with a holder assembly (Fig. 11) comprising a pivotally mounted frame 216 attached to the

centrifuge rotor 214 for removably receiving the container 110, 112 and for positioning the container in multiple positions or orientations as seen in the solid and phantom positions of Figure 10; the container being provided with removable lid portions 120, 122 and access port 118. The centrifuge allows the container to assume a first orientation (solid lines in Fig. 10) where the product in the chamber 114 is subjected to centrifugation and after separation occurs, allows a separated fluid in the chamber 114 to flow via the flow path of the bridge into the second chamber 116 while in a vertical orientation (Col. 9, lines 1-69). Although the adjective "sterile" is not considered a structural limitation as explained below, a primary objective of Raccuglia et al. is the separation of biological substances such as blood which would mandate the container being sterile. Accordingly, sterility is considered to be inherent characteristic of the container in Raccuglia et al.

17. Claims 35-37 are rejected under 35 U.S.C. § 102(e) as being anticipated by Li (USP 5,503,284).

The patent to Li discloses a method of treating fluids including providing a walled container 12 adapted to contain fluids and comprising a first chamber 16, 38 with walls and a second chamber 40 with walls; a bridge 34 connecting a top portion of the first chamber and a top portion of the second chamber for transferring a substance between the chambers when the container is positioned at an angle (Figs. 3-8); the container having a removable lid C and an access port 26.

18. Claims 35-37 are rejected under 35 U.S.C. § 102(b) as being anticipated by McFarland (USP 3,642,163).

The patent to McFarland discloses a method of treating fluids including providing a walled container (Fig. 1) adapted to contain fluids and comprising a first chamber 12 with walls and a second chamber 14 with walls; a bridge 32 connecting a top portion of the first chamber and a top portion of the second chamber for transferring a substance between the chambers when the container is positioned at an angle; the container having a removable lid 18 and an access port (proximate 22).

19. Claims 35-37 are rejected under 35 U.S.C. § 102(b) as being anticipated by Crippa (USP 4,026,433).

The patent to Crippa discloses a method of treating fluids, including biological liquids (Col. 1, lines 6-16) including providing a walled container (Fig. 2) adapted to contain fluids and comprising a first chamber 1 with walls and a second chamber 7 with walls; a bridge 4 connecting a top portion of the first chamber and a top portion of the second chamber for transferring a substance between the chambers when the container is positioned at an angle (Col. 2, lines 31-38); the container having a removable lid 10 and access ports (proximate 3 and 6).

20. Claims 35-37 are rejected under 35 U.S.C. § 102(b) as being anticipated by Onishi (USP 4,294,372).

The patent to Onishi discloses a method of treating fluids including providing a walled container (Fig. 2) adapted to contain fluids and comprising a first chamber A with walls and a second chamber B with walls; a bridge 21a connecting a top portion of the first chamber and a top portion of the second chamber for transferring a substance between the chambers when the container is positioned at an angle (Col. 3, lines 40-56 and col. 4, lines 24-28); the container having a removable lid 23 or 25 and access ports 22 and 24.

21. Claims 43, 44, 45, and 47 are rejected under 35 U.S.C. § 102(b) as being anticipated by Crippa (USP 4,026,433).

The patent to Crippa discloses a method of treating fluids, including biological liquids (Col. 1, lines 6-16) including providing a walled container (Fig. 2) which is rigid (as it is formed from plastic material); the container adapted to contain fluids and comprising a base, a first chamber 1 with walls and a second chamber 7 with walls; the chambers 1 and 7 being adjacent to each other and having adjacent sidewalls; a bridge 4 connecting a top portion of the first chamber and a top portion of the second chamber for transferring a substance between the chambers when the container is positioned at an orientation (Col. 2, lines 31-38); the bridge being formed at the tops of the adjacent sidewalls (Figs. 2 and 4) the container having a removable lid 10 and access ports (proximate 3 and 6).

Furthermore, the product-by-process limitation of claim 44 (i.e., the manner in which the chambers and bridge are formed via molding) does not impart patentability to the claims per MPEP 2113.

Although the adjective "sterile" is not considered a structural limitation as explained below, a primary objective of Crippa is providing a container for holding medical specimens to be analyzed which would mandate the container being sterile. Accordingly, sterility is considered to be inherent characteristic of the container in Crippa.

* * *

With regard to the claim language "sterile", the examiner's position is that the term "sterile" does not impart any specific structure to the container, but is perhaps a product by process limitation as to the manner in which the container is made or the manner in which the container is packaged (e.g., hermetically sealed to maintain sterility). However, the pending claims recite no particular nonobvious process for manufacturing the sterile container, sterilizing the container, or packaging for the container that either imparts sterility to or maintains sterility of the container. Hence, it is not clear how the physical structure of the container changes to define over the prior art simply by labeling it "sterile". Since sterility itself is not considered to impart any unique structural features to define over the applied prior art, and since several of the

prior art devices can reasonably be considered inherently sterile, the rejections are considered proper.

Claim Rejections - 35 U.S.C. § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

23. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

24. Claims 38 and 39 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Raccuglia et al. (USP 3,190,546) in view of Le Veen (USP 3,221,741).

The patent to Raccuglia et al. discloses the recited method of treating physiological products (such as blood) as explained above. Although sterility is considered an inherent characteristic of Raccuglia et al., the patent to Raccuglia et al. does not explicitly disclose that the container is sterile. Assuming, *arguendo*, that the container of Raccuglia et al. is not sterile, the patent to Le Veen teaches that it was common practice as of at least 1962 to process blood in sterile containers (Col. 1, lines 9-15 and lines 40-44). It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified the container of Raccuglia et al. such that it is sterile as taught by Le Veen for the purpose of rendering the container free of microorganisms which could contaminate the materials in the container. Furthermore, the court has held that "[t]he sterilization of containers, when desired, also involves nothing more than the ordinary skill of the art." *In re Piazze and Baxter*, 109 USPQ 34, (CCPA 1956).

25. Claims 38 and 39 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Raccuglia et al. (USP 3,190,546) in view of Weber et al. (USP 3,228,444).

The patent to Raccuglia et al. discloses the recited method of treating physiological products (such as blood) as explained above. Although sterility is considered an inherent characteristic of Raccuglia et al., the patent to Raccuglia et al. does not explicitly disclose that the container is sterile. Assuming, *arguendo*, that the container of Raccuglia et al. is not sterile, the patent to Weber et al. '444 discloses a

container 10, 12 for medical fluids that is sterile. It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified the container of Raccuglia et al. such that it is sterile as taught by Weber et al. '444 for the purpose of eliminating the likelihood for bacteria, fungus, or other extraneous matter to collect in the container and contaminate the sample (Col. 2, lines 10-18). Furthermore, the court has held that "[t]he sterilization of containers, when desired, also involves nothing more than the ordinary skill of the art." *In re Piazze and Baxter*, supra.

26. Claims 43, 44, 45 ,and 47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Crippa (USP 4,026,433) in view of Weber et al. (USP 3,228,444).

The patent to Crippa discloses the recited method of treating physiological fluids as explained above. Although sterility is considered an inherent characteristic of Crippa, the patent to Crippa does not explicitly disclose that the container is sterile. Assuming, *arguendo*, that the container of Crippa is not sterile, the patent to Weber et al. '444 discloses a container 10, 12 for medical fluids that is sterile. It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified the container of Crippa such that it is sterile as taught by Weber et al. '444 for the purpose of eliminating the likelihood for bacteria, fungus, or other extraneous matter to collect in the container and contaminate the sample (Col. 2, lines 10-18). Furthermore, the court has held that "[t]he sterilization of containers,

when desired, also involves nothing more than the ordinary skill of the art." *In re Piazze and Baxter*, supra.

Furthermore, the product-by-process limitation of claim 44 (i.e., the manner in which the chambers and bridge are formed via molding) does not impart patentability to the claims per MPEP 2113.

27. Claims 43, 44, 45, and 46 are rejected under 35 U.S.C. § 103(a) as being unpatentable over McFarland (USP 3,642,163) in view of Weber et al. (USP 3,228,444).

The patent to McFarland (USP 3,642,163) discloses the recited method of treating fluids as explained above. The patent to McFarland does not explicitly disclose that the container is sterile. Assuming, *arguendo*, that the container of McFarland is not sterile, the patent to Weber et al. '444 discloses a container 10, 12 for medical fluids that is sterile. It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified the container of McFarland such that it is sterile as taught by Weber et al. '444 for the purpose of eliminating the likelihood for bacteria, fungus, or other extraneous matter to collect in the container and contaminate the sample (Col. 2, lines 10-18). Furthermore, the court has held that "[t]he sterilization of containers, when desired, also involves nothing more than the ordinary skill of the art." *In re Piazze and Baxter*, supra.

Furthermore, the product-by-process limitation of claim 44 (i.e., the manner in which the chambers and bridge are formed via molding) does not impart patentability to the claims per MPEP 2113.

28. Claims 43, 44, 45, and 47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Onishi (USP 4,294,372) in view of Weber et al. (USP 3,228,444).

The patent to Onishi (USP 4,294,372) discloses the recited method of treating fluids as explained above. The patent to Onishi does not explicitly disclose that the container is sterile. Assuming, *arguendo*, that the container of Onishi is not sterile, the patent to Weber et al. '444 discloses a container 10, 12 for medical fluids that is sterile. It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified the container of Onishi such that it is sterile as taught by Weber et al. '444 for the purpose of eliminating the likelihood for bacteria, fungus, or other extraneous matter to collect in the container and contaminate the sample (Col. 2, lines 10-18). Furthermore, the court has held that "[t]he sterilization of containers, when desired, also involves nothing more than the ordinary skill of the art." *In re Piazze and Baxter*, supra.

Furthermore, the product-by-process limitation of claim 44 (i.e., the manner in which the chambers and bridge are formed via molding) does not impart patentability to the claims per MPEP 2113.

Allowable Subject Matter

29. Claim 40-42 would be allowable if rewritten to overcome the rejections under 35 U.S.C. §§ 112, 251 and to include all of the limitations of the base claim and any intervening claims.

30. Claims 1-31 would be allowable if rewritten to overcome the rejection under 35 U.S.C. § 251.

31. The following is an Examiner's statement of reasons for the indication of allowable subject matter:

The prior art of record does not teach or fairly suggest the movable locking plate that is movable between free and locking positions and which allows the container to assume the first orientation in the free position and the predetermined position when in the locking position.

Amendments to Reissue

Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

Conclusion

32. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The cited prior art is the art cited in the original patent upon which this reissue is based and the newly cited art discloses sterile containers.

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Charles Cooley whose telephone number is ☎ (703) 308-0112.

34. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1700 receptionist whose telephone number is ☎ (703) 308-0651.

Dated: **5 August 2002**

Charles Cooley
Primary Examiner
Art Unit 1723